REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-33 are pending in this case, claims 34-148 having been previously withdrawn under a restriction requirement as drawn to a non-elected invention. Claims 1-33 have been rejected.

By this amendment, claims 1, 16, 18, 19, 29-31 and 33 have been amended. Claims 34-39 have been added.

Attached hereinabove is a marked up version of the changes made to the claims by the current amendment.

Claim Rejections – 35 USC § 112

The examiner has rejected claims 29-32 under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claims 29-32 recite the limitation "said table" in line 1, and that reference to "said table" has insufficient antecedent basis.

Claims 29-32 have been amended to depend from claim 20 rather than from claim 24. Claim 20 recites a "system of claim 17, wherein said recommendation is based on a table of optimal interventions based on expert recommendations." The "table" of claim 20 is the antecedent to the "said table" referred to in amended claims 29-32.

Claim Rejections – 35 USC § 102 - Holupka

The examiner has rejected claims 1-3 and 5-15 under 35 U.S.C. § 102(e) as being anticipated by Holupka et al. in U.S. Pat. 6,256,529. The Examine's rejections are respectfully traversed. Claim 1 has now been amended.

It is the Applicant's opinion that considerations presented below justify the view that the claimed invention is both structurally and functionally distinct from that described by Holupka. However, to further remove any ambiguity in this regard, independent claim 1 and dependent claims 16, 18, and 19 have been amended to more clearly distinguish between the claimed invention and the system described by Holupka.

The Applicant will present arguments below to show that Holupka does not in fact describe a planning system having an interface useable by an operator for specifying loci for insertion of cryoprobes, that Holupka does not include a predictor for predicting effects of a user-specified positioning of cryoprobes, does not provide facilities enabling a user to visualize a predicted result of his simulated surgical intervention, does not provide an evaluator operable to evaluate a user-specified intervention in terms of user-specified intervention goals, does not provide means for displaying predicted short-term and long-term results of a simulated intervention, and does not provide means for recommending a choice among a plurality of user-specified simulated interventions, all of which above-listed facilities are provided by the instant disclosure and described by original, amended, or new claims of the instant application.

The Examiner has rejected independent claim 1, stating that "Holupka discloses a planning system for planning a cryosurgical ablation procedure (col 10:28-33), comprising....a simulator (13, col 4:35-40) for simulating a cryosurgical intervention, which comprises an interface useable by an operator for specifying loci for insertion of cryoprobes (19, patented claim 4) and operational parameters (col. 7:56-63) for operation of cryoprobes for cryoablating tissues...."

In the opinion of the Applicant, Holupka does not in fact present a system having an interface useable by an operator for specifying loci for insertion of cryoprobes, nor does the system he describes provide for user specification of operational parameters for operation of cryoprobes (nor, equivalently, for the operation of seed-placing catheters).

→ Col 9 4:6

With respect to the nature of the interface described by Holupka, the attention of the Examiner is first drawn to two passages in which Holupka discusses the positioning of radioactive seeds during an intervention. The first passage, from Holupka's description of prior art, col. 2, lines 36-46:

> Once the 3D contour data has been obtained for the prostate volume, a radiation therapy plan which describes the positions of the radioactive seeds within the prostate is developed. This plan attempts to optimize the dose to the prostate, minimize the dose to surrounding healthy tissue, and minimize dose inhomogeneity. The positions of the radioactive seeds are constrained to fall within the catheter tracks, since the seeds are placed within the prostate transperineally via these catheters. The result of the pre-plan describes the positions and strengths of the radioactive seeds within the catheter which optimizes the dose to the prostate.

As explained by Holupka at col. 2 lines 20-25 and at col. 2 lines 48-51, the positions of the tracks mentioned in the above paragraph are themselves constrained by the holes in the plastic rectangular template which is an integral part of the system.

Attention is now drawn to a second passage, from col. 7 lines 22-34:

> As described above, in the routine process of brachy-therapy planning, the patient undergoes an initial volumetric ultrasound scan using the probe 12. This scan is done before the radiation therapy planning, the ideal positions of the radioactive seeds 18 (see FIG. 1) within the prostate are determined. This ideal seed distribution is optimized to deliver a dose distribution within the prostate that will deliver all the radiation dose to the target volume only, while sparing the surrounding healthy tissue sach as the rectum and bladder. The optimal positions of the seeds 18 and the optimal position of the needles 19 are recorded for later use in the operating room when the needles 19 are loaded into the patient.

Holupka goes on to describe, in lines 38-55, a procedure by which the optimized dosage and position of the radioactive seeds is determined.

It may be noted that if the catheter tracks are described as constrained by the positions of the holes in the plastic implant template, and the dosage and position of the radioactive seeds is determined by the software described in column 7, lines 38-55, then there is in fact nothing in Holupka's disclosure that states or implies that the user of his system has a free choice in describing where his cryoprobes (or seed catheters) are to be placed, nor that the operator has an option of himself specifying dosages.

col 9 4-6

In sharp contrast, page 46 lines 12-20 of the instant application describes a user interface which does allow a user to specify both position and functional parameters of his simulated cryoprobes:

> Simulator 260 comprises a displayer... and an interface 264 useable by an operator for specifying loci for insertion of simulated cryoprobes 266 and operation parameters for operation of simulated cryoprobes 266 for cryoablating tissues. Thus, an operator (i.e. a user) can use simulator 260 to simulate a cryoablation intervention, by using interface 264 to command particular views of model 258, and by specifying both where to insert simulated cryoprobes 266 into an organ imaged by model 258, and how to operate cryoprobes 266.

The difference between the two systems is made clear if one asks the question "Can this simulator be used to provide feedback to a surgical student with respect to his simulated ablation operation." At this point it has been shown that a user of the invention described in the instant application can use the user interface to specify placement and paramaters of operation of a cryoprobe or of a plurality of cryoprobes, yet a user of the invention of Holupka's disclosure cannot do so. The instant invention can be used as a training tool; Holupka's invention, in this respect, cannot.

Consequently it is the opinion of the Applicant that amended claim 1, now specifying (claim 1, c, i) "an interface useable by an operator for specifying operator-specified loci for insertion of cryoprobes and operational parameters for operation of said cryoprobes for cryoablating tissues" is not anticipated by Holupka ('529).

With respect to original claims 11-12 and new claims 34-37, the Applicant will now show that Holupka's system does not predict the results of a user-specified intervention, nor could Holupka's system provide feedback to a user (such as a surgical student) on a user-specified simulated intervention, even if Holupka's system did comprise an interface useable by a user to specify such a simulated intervention. Holupka does not describe such a feedback mechanism, nor does he teach a use of his system involving feedback to the *plan* of an intervention.

First, it may be noted that the feedback provided by Holupka's system is entirely limited to feedback during the real-time surgury phase of operation. Thus, in col. 7 line 63 to col. 8 line 1: "As the real needles 19 are inserted into the prostate, their positions relative to the ideal needle placemcnts based on the dose plan can be monitored in real time. Any deviation of the position of a given needles 19 can be quickly and accurately readjusted so as to follow the path of the ideal needles 19." A similar description appears in col. 9, lines 1-4: "As mentioned above, if the pre-planned, optimized nccdles 19 are displayed, the physician can then see the position of the actual needles 19 as they are being inserted relative to the optimal placement." In other words, the *system* does not respond to the *plan;* rather, the *operator,* utilizing visualization modalities provided by the system, is enabled to respond to and correct his own actions in executing the plan, by comparing his planned behavior to his actual behavior. This does not constitute feedback to the user about the plan, nor does it constitute a prediction of the effect of the plan on tissues treated according to the plan.

The Examiner discusses the existence of a predictor in Holupka's system, in a paragraph discussing claims 11-15. The Examiner states "The demarcatoin of zones by Holupka is equivalent to disclosing a predictor for predicting probe effects on tissue. Holupka is able to define the specific dimensions of the disclosed zones for each surgery, thereby allowing the operator to better control the destruction of targeted tissue while preserving non-targeted tissue."

However, in the opinion of the Applicant, the demarcation of zones by Holupka does not constitue a *prediction* createcl by Holupka's *system.* Holupka states clearly that demarcation of zones is a *user-specified* function. See col. 6, lines 47-63: "On each of the views, one can define, draw and edit contours using conventional computer software...." Holupka does not anywhere indicate that his system is

capable of a diagnostic interpretation of received ultrasound images; it is the user, looking at the images, who marks the borders of various objects to be ablated or protected. Neither are the demarcated zones predictions of the results of a surgical intervention, simulated or otherwise. They are, as it were, part of the definition of the problem to be solved by the surgery, and not a part of a system-planned solution. Moreover, the demarcated zones can not in any case be seen as a prediction of the results of a user-planned intervention, because, as shown above, at the planning phase of the procedure described by Holupka, the *user* has not defined an intervention. Thus, claim 11 is not anticipated by Holupka.

With respect to claim 12 and new claims 34-37, it may further be noted that Holupka's system does not provide for visual presentation of the *results* of the specified placements and operating parameters of his cryoprobes/seed-catheters. In other words, even if the Examiner were to reject the interpretation that the user does not specify the location and operating parameters of Holupka's probes, Holupka's disclosure would still not anticipate claim 12 and claims 34-37, because Holupka's graphics display, in its various forms, is of what he calls the "optimal" probe positions (whether user-specified or, as the Applicant contents, system specified), or of real-time images of actual probes, or of both. None of these options comprises visual display of a predicted result of operation of the "optimal" probes under "optimal" operating parameters. Nor is there an indication that the calculations described in lines 38-55 of column 7 constitute a *predictive* device. In any case, Holupka's system is operable to present a graphical display of an *intervention*: the system displays the optimal positions of the probes, as defined by the system. It does not present any kind of graphical display of the *predicted results* of the designated intervention. This may be contrasted with the instant disclosure, which states on page 48, lines 7-12:

> Predictor 290 serves for predicting the effect on tissues of a patient, if a planned operation of cryoprobes 266 at the operator-specified loci is actually carried out according to the operator-specified operational parameters. Predictions generated by predictor 290 may optionally be displayed by displayer 262 as part of integrated image 268, in the common virtual space of image 268.

Thus, claims 11-12 and 34-37 are not anticipated by Holupka.

Claims 13-15 refer to an evaluator 300 for comparing an effect predicted by predictor 290 to an operator-defined goal of said procedure. Since, as has been shown above, Holupka's system does not comprise a predictor such as predictor 290, operable to predict an effect of operation cryoprobes at user-defined positions according to user-defined parameters, Holupka's system cannot be said to anticipate claims 13-15.

With respect to claim 16 and claims dependent thereon, claim 16 has been amended to avoid ambiguity. Claim 16 now defines a system comprising a recommender for recommending cryosurgical procedures to an operation, said recommendation being based on goals of a cryoablation procedure, said goals being specified by an operator, and further being based on a three-dimensional model of said site, *and further being based on operator-selected loci* for placement of simulated cryoprobes. Since, as has been shown above, Holupka's system does not comprise cryoprobes at operator-selected loci, claim 16, and claims dependent thereon, are not anticipated by Holupka.

Claim Rejections – 35 USC § 103(a) - Holupka

The Examiner has rejected claims 24, 25, and 29-30 under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690).

The Examiner has rejected claim 26 under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690) and further in view of Crockett ('488).

The Examiner has rejected claims 31 and 32 under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690) and further in view of Fenn et al. ('426).

Claims 24-33 depend from claim 16 which has been amended as described above. The Applicant has demonstrated above, in the context of discussing the Examiner's 35 USC 102 claim rejections, that Holupka's system does not relate to a system involving user-specified loci for placement of simulated cryoprobes, nor does it relate to user-supplied parameters for operation of such cryoprobes, nor to prediction of the results of operating such user-placed cyroprobes according to user-specified operational parameters, nor to recommending cryoablation (or seed placement and dosage) proceedures relating to user-designated positions and operating parameters for cryoprobes. Claims 1 and 16 have been amended, as described above. Claim 1 reads on systems having an interface useable by an operator for specifying operator-specified loci for insertion of cryoprobes and for specifying operator-specified operational parameters for operation of those inserted cryoprobes for cryoablating tissues. Claim 16 reads on a recommender operable to recommend cryosurgical procedures, based on operator-selected loci for cryoprobes.

Accordingly, in the opinion of the Applicant, Holupka does not anticipated amended claims 1 and 16, and consequently does not anticipate claims dependent on claim 1 and on claim 16. In particular, 24, 25, and 29-30 under 35 U.S.C. 103(a) are not unpatentable over Holupka in view of Mikus et al. ('690), claim 26 is not unpatentable over Holupka in view of Mikus et al. ('690) and further in view of Crockett ('488), and claims 31 and 32 are not unpatentable over Holupka in view of Mikus et al. ('690) and further in view of Fenn et al. ('426).

In view of the above amendments and remarks it is respectfully submitted that claims 1-39 are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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Encl.:
A two month extension fee.